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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/567,661

09/06/2006

Andrew Michael Lindsay Lever

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EXAMINER

MARVICH, MARIA

ART UNIT

PAPER NUMBER

1633

MAIL DATE

DELIVERY MODE

08/19/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/567,661	Applicant(s) LEVER ET AL.	
	Examiner MARIA B. MARVICH	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 May 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 49 and 50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 February 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/6/06</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims pending in the application are 1,2,4,5,7,13-16,19,21,23,25,26,28-31,33,34,36-42,49-51 and 53-55.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 1,2,4,5,7,13-16,19,21,23,25,26,28-31,33,34,36-42,51 and 53-55.

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DETAILED ACTION

This office action is in response to an amendment filed 5/1/09. Claims 1, 2, 4, 5, 7, 13-16, 19, 21, 23, 25, 26, 28-31, 33, 34, 36-42, 49-51 and 53-55 are pending.

Election/Restrictions

Applicant's election with traverse of Group V claims 49 and 50) in the reply filed on 5/1/09 is acknowledged. The traversal is on the ground(s) that claims I and III be examined because the subject matter found in these claims are incorporated into claims 49 and 50. This is not found persuasive because of the following reasons. Claims 49 and 50 require the virus of claim 33 wherein the virus is produced by the process of claim 1. As to the examination of claim 1 with the method of Group V. The two lack unity of invention as unity as the virus are known in the art, hence the virus which is the inventive feature in this case does not form a special general inventive concept. Furthermore, products made by the process within a process claim do not require the process by which they were made. For example, the process of claim 1 is not required as the virus can be made by other methods. MPEP 2112.02 teaches "Product-BY-Process Claims are not limited to the manipulations of the recited steps, only the structure implied by the steps, [E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product." As to examination of product and process together, this combination of groups was indicated as related by inclusion of the standard under *in re Ochia* on page 4 the restriction requirement mailed 4/3/09. However, in order to garner rejoinder of product and process claims, the product must have been elected and found allowable. Applicants have elected the process claims and hence rejoinder is not proper.

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The requirement is still deemed proper and is therefore made FINAL. Claims 1, 2, 4, 5, 7, 13-16, 19, 21, 23, 25, 26, 28-31, 33, 34, 36-42, 51 and 53-55 are withdrawn, claims 49 and 50 are under examination.

Information Disclosure Statement

An IDS filed 9/6/06 has been identified and the documents considered. The signed and initialed PTO Form 1449 has been mailed with this action.

Claim Objections

Claims 49 and 50 are objected to because of the following informalities: claims 49 and 50 comprise non-elected subject matter and should be drafted in independent form. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 49 and 50 are rejected under 35 U.S.C. 102(b) as being anticipated by Chang et al (US 6,207,455; see entire document).

Chang et al teach HIV-2 recombinant vectors comprising nucleotide sequences of interest that can be within pseudotyped capsids. These vectors comprise HIV-2 packaging signals (see

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e.g. col 5 and bridging ¶ col 5-6). Specifically, Chang et al teach use of transducing vectors to transduce packaging cell lines wherein packaging vectors are used to produce the packaging cell lines. Specifically, Chang et al teaches, “To construct a lentiviral ‘transducing vector’ based on HIV-2 or SIV, a construct similar to the pTVA vector is made which contains the SIV or HIV-2 packaging signals (from 3' of the PBS to the extended gag sequences). These HIV-2 and SIV transducing vectors (pTV2 and pTVS) are first tested in co-transfection experiments using pH2P or pSIVP. The transduction efficiency is compared to the HIV-1 vector constructs carrying the reporter gene lacZ (example 5).” Furthermore, Chang et al teach that, “Thus, the recombinant lentivirus may be recombinant HIV-1, HIV-2, SIV, or a virus comprised of portions of more than one lentiviral species (e.g., a hybrid, comprised of portions of HIV-1 and HIV-2, or HIV-1 and SIV, etc.)” For example, the packaging vector used to create packaging cell lines uses SIV as a reference vector or to make the packaging cell lines (see e.g. claim 4 and 8).

Hence, applicants teach methods of constructing a hybrid virus wherein the envelope protein is from SIV and the transducing vector comprises a nucleotide sequence of interest and an HIV2 packaging sequence (see e.g. col 1, line 19-35). Furthermore, Chang et al teaches that these viruses are used for gene therapy or vaccines. These vectors then deliver antigenic or therapeutic proteins or peptides to an individual (see e.g. abstract).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARIA B. MARVICH whose telephone number is (571)272-0774. The examiner can normally be reached on M-F (7:00-4:00).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, PhD can be reached on (571)-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Maria B Marvich, PhD
Primary Examiner
Art Unit 1633

/Maria B Marvich/
Primary Examiner, Art Unit 1633